Office Action Summary

Application No.	Applicant(s)
09/101,672	BARTLETT et al.
Examiner	**Group Art Unit**
Everett White	1623

☒ Responsive to communication(s) filed on *Feb 1, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *12-17, 20-26, and 29* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *12-17, 20-26, and 29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Amendment C filed February 1, 2000 has been received and entered into the record.

2. Claims 12-17, 20-26 and 29 are pending in the case.

3. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

35 USC 103 Rejection

4. Claims 12-17, 20-26 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276) for the reasons already of record on page 2 of the Office Action mailed December 6, 1999.

5. Applicant's arguments filed February 1, 2000 have been fully considered but they are not persuasive. Applicants argue that their claimed composition, a small quantity of compound 2 to the main active component compound 1, results in a marked increase in the activity of the combination preparation. To support their argument Applicants refer to Table 1 of the instant specification. However, the data disclosed in Table 1 does not set forth any unexpected results in view of the composition that is actually claimed and used in the claimed methods since Table 1 sets forth data wherein a 10 mg/kg dose of compound 1 used alone shows activity (74% decrease in paw volume and 58% decrease in arthritis index) that appears to be better than the combination of 4.85 mg/kg dose of compound 1 with 0.15 mg/kg dose of compound 2 (10% decrease in paw volume and 5% decrease in arthritis index) and the combination of 4.5 mg/kg dose of compound 1 with 0.5 mg/kg dose of compound 2 (46% decrease in paw volume and 35% decrease in arthritis index). The combination of 4.85 mg/kg dose of compound 1 with 0.15 mg/kg dose of compound 2 as well as the combination of 4.5 mg/kg dose of compound 1 with 0.5 mg/kg dose of compound 2 fall within the instantly claimed limitation of the second component having a concentration from about 0.3% to 50% of the first component.

Applicants arguments with regard to the experiments disclosed in the Bartlett et al patent whereby compound 1 and compound 2 are tested separately is not persuasive since the Bartlett et al patent does suggest the preparation and administration of pharmaceutical products which

comprises unit dosages of compounds 1 and 2 together in one composition. See the sentence at column 6, lines 28-31 of the Bartlett et al patent which discloses pharmaceutical products in dosage units, "each unit containing as active ingredients a defined dose of compound 1 and/or 2." Also see the same paragraph (column 6, line 31) wherein the dose amount of the pharmaceutical product can be as small as 10 mg for a solid dosage unit, which meet the limitation disclosed in the instant claims for the range of the total amount of compound 2 that can be present in the claimed composition.

Accordingly, the rejection of the claims as being unpatentable over the Bartlett et al patent is maintained.

6. All the pending claims (12-17, 20-26, and 29) are rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

White

June 2, 2000

GARY GEIST
SUPERVISORY PATENT EXAMINER
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